

US Patent Application No. 10/663,506
Response to OA mail date 11/15/2006
February 9, 2007

REMARKS / ARGUMENTS

Claims 1-6 and 10- 20 are pending. Claims 7-9 have been cancelled, without prejudice.

Support for the amendment of claim 1 and new claim 20 is found on page 3, lines 17 – 25. New claim 20 is further supported in the examples.

No new matter is added by this amendment.

35 USC § 102(e)

The Examiner has rejected claims 1, 2, 4 and 6 under 35 USC 102(e) as being anticipated by Rubino et al. (US Patent Publication No. 2004/0167152 A1).

Rubino teaches parenteral formulations of CCI-779 containing a parenterally acceptable cosolvent, an antioxidant, a diluent solvent, and a surfactant. From this it is clear that *Rubino* is teaching liquid formulations of CCI-779. *Rubino* does not teach of a solid oral granulation containing CCI-779 with the excipients as recited in the present claims.

Reconsideration and withdrawal of the rejection is requested.

35 USC §103

Claims 3, 5 and 10-19 are rejected under 35 USC 103(a) as being unpatentable over Rubino et al, in view of Patel, US 6,248,363. It is noted that the examiner's remarks address Azrolan, US 2002/0013335.

Applicants respectfully request that the rejection under 35 USC § 103 be withdrawn.

The combined teachings of the available prior art fail to suggest the solid CCI-779 formulation of the invention. Further, none of the prior art recognizes the problem to which the present invention is directed, *i.e.*, providing a highly bioavailable non-micronized CCI-779 formulation that avoids dissolution and

US Patent Application No. 10/663,506
Response to OA mail date 11/15/2006
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instability problems associated with the formation of the CCI-779 compositions of the prior art by compression.

It is noted that Rubino *et al.* was published on August 26, 2004, which is well after the priority date and filing date of the instant invention, which is September 17, 2002 and September 15, 2003, respectively. 35 USC § 103(a) specifically states that the invention has to be “obvious at the time the invention was made”, which makes any reliance on Rubino *et al.* contrary to this statute. Accordingly, Rubino *et al.* qualifies only as prior art under 35 USC § 102(e). Since both applicants are owned by Wyeth [into which American Home Products was merged], this document is not available as prior art.

Patel describes solid carriers, including a substrate and an encapsulation coat. There is no suggestion of a formulation containing CCI-779 (temsirolimus). Azrolan describes methods of treating cardiovascular disease with a rapamycin which may include CCI-779. General information regarding excipients useful in formulations is provided.

However, absent recognition of the problem on which this invention focuses, nothing in the cited documents suggests the combination of excipients provided by the present formulation, nor could the advantages thereof be predicted.

For the reasons set forth above, the Examiner is respectfully requested to reconsider and withdraw the rejection under 35 USC 103(a).

Double Patenting

Claims 1, 2 and 4-6 are provisionally rejected on the ground of non-statutory obviousness type double patenting over claims 55, 58-61, 65 and 72-72 of copending Application No. 10/930,487. [AM101383].

Applicants respectfully traverse this rejection.

Copending application 10/930,487 contains claims drawn to formulations containing amorphous CCI-779. In contrast, the present application contains claims

US Patent Application No. 10/663,506
Response to OA mail date 11/15/2006
February 9, 2007

to CCI-779 with the specified excipients. Applicants believe that the claims of the two applications are nonobvious over the other.

Reconsideration and withdrawal of this rejection is requested.

Claims 1, 2 and 4-6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7-8 and 11 of copending application no. 11/030,685.

Copending application 11/030,658 contains claims drawn to micronized CCI-779 and formulations containing same. In contrast, the present application contains claims to non-micronized CCI-779 with the specified excipients. Applicants believe that the claims of the two applications are nonobvious over each other.

Reconsideration and withdrawal of this rejection is requested.

In view of the above amendments and these remarks, Applicants respectfully request favorable consideration of the claims.

The Director is hereby authorized to charge any deficiency in any fees due with the filing of this paper or credit any overpayment in any fees to our Deposit Account Number 08-3040.

Respectfully submitted,

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